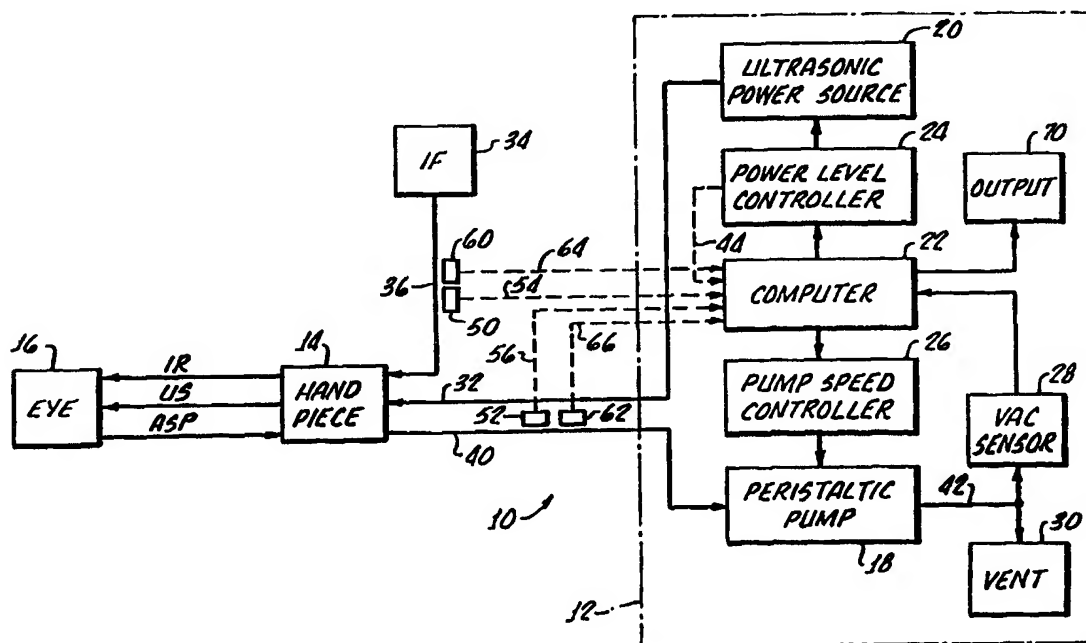




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 9/007	A1	(11) International Publication Number: WO 99/45868 (43) International Publication Date: 16 September 1999 (16.09.99)
(21) International Application Number: PCT/US99/04494 (22) International Filing Date: 1 March 1999 (01.03.99) (30) Priority Data: 09/037,638 10 March 1998 (10.03.98) US (71) Applicant: ALLERGAN SALES, INC. [US/US]; 2525 Dupont Drive, Irvine, CA 92612 (US). (72) Inventors: KADZIAUSKAS, Kenneth, E.; 49 Grassy Knoll Lane, Las Flores, CA 92688 (US). ROCKLEY, Paul, W.; 15 Mattina Drive, Newport Coast, CA 92657 (US). (74) Agents: BARAN, Robert, J. et al.; Allergan Sales, Inc., 2525 Dupont Drive, Irvine, CA 92612 (US).		(81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.

(54) Title: TEMPERATURE CONTROLER AND METHOD FOR PHACOEMULSIFICATION



(57) Abstract

Control apparatus (12) for an ultrasonic phacoemulsification handpiece (14) utilizes flow rates and temperature measurements as well as power provided to a handpiece (14) for calculating an energy balance over a time interval and in response thereto, regulating power and/or fluid flow to and from the handpiece (14).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

TEMPERATURE CONTROLER AND METHOD FOR PHACOEMULSIFICATION

5 The present invention is generally directed to apparatus and a method for controlling power delivery to an ultrasonic phacoemulsification handpiece as well as controlling fluid flow to and from an eye during ocular surgery with the phacoemulsification handpiece. More
10 particularly, the invention is directed to apparatus and a method for controlling phaco power delivery and/or fluid flow based upon the amount of thermal energy delivered to an eye over a specific period of time.

15 Phacoemulsification of cataractic lenses is a medically recognized technique. The method generally includes making of a corneal incision and the insertion of a hand held surgical implement, i.e., handpiece, which includes a needle which is ultrasonically driven in order
20 to emulsify the eye lens. Simultaneously, with this emulsification, a fluid is inserted for irrigation of the emulsified lens and a vacuum provided for aspiration of the emulsified lens and inserted fluids.

25 In order to maintain normal pressure within the eye, a balanced salt solution is provided as an irrigation fluid and typically supplied from an elevated chamber. Importantly, the irrigation and aspiration of fluid through the eye must be carefully monitored in order to
30 maintain normal pressure within the eye during surgical procedures. For example, an underpressure condition may cause distortion of the eye which often may interfere with surgical procedures. On the other hand, overpressure may cause damage to the eye.

35

 As hereinabove noted, pressure in the eye may be controlled by physical elevation of the source of

irrigation fluid interconnected to the phacoemulsification handpiece. Aspiration of fluid is typically controlled through the use of peristaltic pump or the like.

5

It should be appreciated that the control of irrigation and aspiration fluids is a dynamic problem. For example, during surgical procedures, fragments of broken tissue may temporarily block an aspiration line or
10 the handpiece. This may lead to a differential pressure which is typically accommodated by stopping or slowing aspiration flow through the regulation of the peristaltic pump connected to the aspiration line.

15 During aspiration of the lens and aspiration fluid, particles may restrict the aspiration flow from the eye through an aspiration port in the tip of the phacoemulsification handpiece. In order to clear this occlusion, vacuum levels may be increased to create a
20 greater differential pressure across the occluding particle in an effort to move the particle downstream and away from the eye. Typically, particles require much higher force to start movement than it takes to continue movement of the particle to the peristaltic pump. Once
25 a particle moves, it creates a subsequent volume of fluid to take up the space it once occupied. This volume may be momentarily larger than the volume of fluid in the eye, therefore, producing a momentary-dimpling of the eye.

30

It has been shown that the pressure sensing of this condition is well within the operation of the phaco machine.

35 However, of further consideration regarding the utilization of phacoemulsification handpiece, is the amount of power delivered to the lens by the handpiece in

order to fragment the lens. If too much power is delivered to the handpiece, without concomitant fluid or cooling irrigation fluid, local temperatures of the eye may rise to a level causing localized trauma. On the other hand, the entire eye may be heated during the procedure within the anterior chamber which may cause damage. Thus, it is important to not only control the power delivery of a phacoemulsification handpiece, but to provide a means for calculating elevated anterior chamber temperatures in order to prevent any tissue damage due to excess delivered power. Such damage can occur within one to two seconds under adverse heating conditions.

It should be appreciated that in combination with the occlusion of the phacoemulsification needle, as hereinabove described, the fluid flowing from the eye can vary considerably. Thus, heat is not removed from the eye in a generally continuous basis, but, of course, is dependent upon the actual fluid flow as a function of time. Heretofore, consoles for providing irrigation fluid and power of an ultrasonic phacoemulsification handpiece and aspirating fluid from the eye during ocular surgery, have not taken into account energy and power considerations nor utilized same for controlling the operation of the phacoemulsification handpiece.

The present apparatus and method provide for such operation.

30 SUMMARY OF THE INVENTION

Control apparatus, by itself, or for use in a control console for providing irrigation fluid and controlling power to an ultrasonic phacoemulsification handpiece and aspiration from an eye during ocular surgery, generally includes a means for monitoring energy provided to the handpiece and means for monitoring energy

removed from the eye by aspirated fluid. In connection therewith, a computer responsive to input from the means for monitoring power provided and removed, provides a means for calculating an energy balance over a time
5 interval and, accordingly, regulating the power provided to the handpiece. The power may be regulated by changing the duty cycle thereof.

In addition, regulation of the fluid flow may also
10 be performed in response to the energy balance calculation.

More particularly, the means for monitoring power removed from the eye may include a means for measuring
15 the flow rate of the aspirated fluid and/or irrigation fluid and may further include a means for measuring a temperature difference between the irrigation fluid and the aspirated fluid.

Additionally, output means, which is responsive to the computer means, may provide an indication of eye temperature based upon the energy balance. Specifically, the output means may provide an alarm at a selected eye temperature level. This enables a continuous monitoring
20 of the eye temperature and, in addition, either visual or audible alarm, may be provided at any selected level in order to attract attention to an energy imbalance in order to prevent thermal damage to eye tissue.

Correspondingly, a method for regulating fluid flow and power to an ultrasonic phacoemulsification handpiece, includes the steps of monitoring power provided to the handpiece, monitoring power removed from the eye by the aspirated fluid and calculating, in response to input
30 from the steps of monitoring the power provided and the power removed, an energy balance over time interval, with subsequent regulation of the power provided to the
35

handpiece and fluid flow of the irrigation fluid and aspiration fluid.

5 DETAILED DESCRIPTION OF THE DRAWINGS

The advantages and features of the present invention will be better understood by the following description, when considered in conjunction with the accompanying
10 drawings, in which:

Figure 1 is a block diagram of control apparatus in accordance with the present invention; and

15 Figure 2 is a plot of fluid transfer as a function of Phaco power displayed during a phacoemulsification procedure.

Turning now to Figure 1, there is shown, in
20 functional block diagram form, a phacoemulsification system. The system 10 includes a control console 12 for providing irrigation fluid and power to an ultrasonic phacoemulsification handpiece 14, and aspirating fluid from an eye 16 during ocular surgery. The console 12
25 includes a variable speed peristaltic pump 18 which provides a vacuum source, a source of pulsed ultrasonic powers 20, and a microprocessor computer 22, an ultrasonic power level controller 24 and a pump speed controller 26. A vacuum sensor 28 provides input to the
30 computer 22 representing a vacuum level on an input side of the peristaltic pump 18. Suitable venting is provided by vent 30. This apparatus and availability is described in greater detail in U.S. Patent No. 5,700,240 which is incorporated herewith in its entirety for describing a
35 control console 12 suitable for use in the present invention.

The console 12 supplies ultrasonic power on line 32 to the handpiece 14 and an irrigation of fluid source 34 is coupled to the handpiece 14 through line 36. The irrigation fluid and ultrasonic power applied by the
5 handpiece 14 to a patient's eye, which is indicated diagrammatically by block 16. Aspiration of the eye 16 is achieved through line 40.

The power level controller 24 provides a means from
10 monitoring power provided to the handpiece 14 by the console 12 and an output indicating a signal corresponding to the power provided to the handpiece 14 may be separately imputed to the computer 22 as indicated by the dashed line 44.

15

Any suitable temperature sensors 50, 52 connected to the computer 22 by lines 54, 56 and flow sensors 60, 62 interconnected to the computer by lines 64, 66, respectively, provide a means for monitoring power
20 removed from the eye 16 by aspirated fluid. The temperature sensors 50, 52 and flow sensors 60, 62 may be of any suitable type. Since the flow rates and temperature of the aspiration and irrigation fluids are known, as well as the power provided to the handpiece,
25 an energy balance can be calculated by the computer.

Energy balance, as the term is used herein, assumes flow through the handpiece which is not chemically changed, i.e., no chemical reaction of the fluid occurs
30 within the eye 16 or the handpiece 14.

The microprocessor computer 22 accordingly is capable of determining cumulative phaco power delivered over a period of time as well as the cumulative fluid
35 removed from the eye by the peristaltic pump 16. Under the further assumption of a tight wound and minimal fluid leakage, aspiration flow and irrigation fluid are

equivalent in the eye system. Therefore, a correlation is established between the fluid flow, phaco power and heat generation in the handpiece 14. In fact, empirically, the flow rate of irrigation/aspiration
5 fluids may be utilized to determine the eye temperature given the heat input by the phaco power provided by the handpiece. In this instance, the fluid temperatures need not be continually measured or monitored.

10 As hereinabove noted, decreasing flow coupled with phaco power deployment over extended time may result in burns or chamber heating.

The computer 22 utilizes either a look-up table or
15 algorithm to determine an energy balance and whether the control console 12 should continue with existing power and fluid settings or switch to modified settings which may be preprogrammed by a user. In addition, the computer may modulate the phaco power level or duty cycle
20 based upon the level of a "heat factor" determined by the energy balance.

In addition, the computer 22 may provide an output indicated by the block 70, which may be of any suitable
25 output device or alarm, for providing an indication of high temperature based on the energy balance.

An example of a heat factor determination with corresponding system response is shown in Figure 2, which
30 represents an algorithm for handpiece 14 operation.

Several methods may be utilized to determine the heat factor including mathematical algorithm or a look-up table contained within system memory. Figure 2
35 illustrates one way in which a heat factor may be determined from a two dimensional matrix. Figure 2 also demonstrates one example of how a system may be

programmed to respond based upon the determined heat factor within this two dimensional matrix.

5 A combination of change in phaco power as well as duty cycle is shown as a response to ultrasonic power and fluid transfer within a given increment of time. By monitoring the fluid removed from the eye by the aspiration means utilizing a microprocessor, the quantity of fluid capable of transferring heat away from the eye
10 in a given increment of time can be determined or approximated. In addition, the system 10 is also capable of monitoring the cumulative ultrasonic energy deployed into the eye 16 in a given increment of time by utilizing a microprocessor 22 to either calculate energy directly
15 from the power level utilized by the surgeon via footpedal control, not shown, or by monitoring equivalent phaco time. Equivalent phaco time is the average percent power setting on the system used by the surgeon divided by 100. Heat generation within the eye 16 is a function
20 of the energy deployed. In response to these two calculations, a coordinate is determined within the two dimensional matrix. The system 10 response to this coordinate is either provided pre-programmed into the system or determined by the surgeon and programmed and/or
25 modified in either a preoperative or inter-operative manner.

The equivalent time set forth in Figure 2 corresponds to full duty cycle of one second. That is,
30 if the handpiece 14 is powered at one-half duty cycle, then the active time would be 2 sec., corresponding to an equivalent time of 1 sec. full duty cycle.

Although there has been hereinabove described
35 controlled apparatus in accordance with the present invention, for the purpose of illustrating the manner in which the invention is used to advantage, it should be

appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art, should be considered to be within the scope
5 of the present invention as defined in the appended claims.

10

15

WHAT IS CLAIMED IS:

1. In a control console for providing irrigation
5 fluid and energy to an ultrasonic phacoemulsification
handpiece and aspirating fluid from an eye during ocular
surgery, control apparatus for regulating fluid flow and
power, said control apparatus comprising:
 means for monitoring energy provided to the
10 handpiece by the control console;
 means for monitoring energy removed from the
eye by aspirated fluid; and
 computer means, responsive to input from the
means for monitoring energy provided to the handpiece
15 and the means for monitoring energy removed from the eye,
for regulating the energy provided to the handpiece.
2. The control apparatus according to claim 1
wherein the means for monitoring energy removed from the
20 eye includes means for measuring a flow rate of the
aspirated fluid.
3. The control apparatus according to claim 2
wherein the means for monitoring energy removed from the
25 eye further comprises means for measuring a temperature
difference between the irrigation fluid and the aspirated
fluid.
4. The control apparatus according to claim 1
30 wherein the control means includes means for regulating
the duty cycle of power provided to the handpiece.
5. The control apparatus according to claim 3
further comprising output means, responsive to said
35 computer means, for providing an indication of eye
temperature based on the energy balance.

6. The control apparatus according to claim 5 wherein said output means provides an alarm indication at a selected eye temperature level.

5 7. Control apparatus for providing fluid and power to an ultrasonic phacoemulsification handpiece during ocular surgery on an eye, said control apparatus comprising:
 means for monitoring energy provided to the
10 handpiece;
 means for monitoring energy removed from the eye; and
 computer means, responsive to input from the means for monitoring energy provided and the means for
15 monitoring energy removed, for calculating an energy balance over a time interval and regulating the power and fluid provided to the handpiece.

8. The control apparatus according to claim 7
20 further comprising means for providing irrigation fluid to the handpiece and means for aspirating fluid from the eye.

9. The control apparatus according to claim 8
25 wherein the means for monitoring energy removed from the eye includes means for measuring a flow rate of the aspirated fluid.

10. The control apparatus according to claim 9
30 wherein the means for monitoring energy removed from the eye further comprises means for measuring a temperature difference between the irrigation fluid and the aspirated fluid.

35 11. The control apparatus according to claim 7 wherein the control means includes means for regulating the duty cycle of power provided to the handpiece.

12. The control apparatus according to claim 10 further comprising output means, responsive to said computer means, for providing an indication of eye temperature based on the energy balance.

5

13. The control apparatus according to claim 12 wherein said output means provides an alarm indication at a selected eye temperature level.

10 14. In a control console for providing irrigation fluid and energy to an ultrasonic phacoemulsification handpiece and aspirating fluid from an eye during ocular surgery, control apparatus for regulating fluid flow and power, said control apparatus comprising:

15 means for monitoring energy provided to the handpiece by the control console;

computer means, responsive to input from the means for monitoring energy provided and the means for monitoring energy removed, for regulating the energy
20 provided to the handpiece, and regulating fluid flow of the irrigation fluid and aspirated fluid.

15. The control apparatus according to claim 14 wherein the means for monitoring energy removed from the
25 eye includes means for measuring a flow rate of the aspirated fluid.

16. The control apparatus according to claim 15 wherein the means for monitoring energy removed from the
30 eye further comprises means for measuring a temperature difference between the irrigation fluid and the aspirated fluid.

17. The control apparatus according to claim 16
35 further comprising output means, responsive to said computer means, for providing an indication of eye temperature based on the energy balance.

18. The control apparatus according to claim 17 wherein said output means provides an alarm indication at a selected eye temperature level.

5 19. In a control console for providing irrigation fluid and energy to an ultrasonic phacoemulsification handpiece and aspirating fluid from an eye during ocular surgery, a method for regulating fluid flow and energy, the method comprising the steps of:

10 monitoring energy provided to the handpiece;
 monitoring energy removed from the eye by aspirated fluid; and
 calculating, in response to input from the steps of monitoring energy provided and energy removed,
15 an energy balance over a time interval and regulating the power provided to the handpiece and fluid flow of the irrigation fluid and aspirated fluid.

20 20. The method according to claim 19 wherein the step of regulating the energy provided to the handpiece includes regulating the duty cycle of the power provided to the handpiece.

25 21. A method for regulating fluid flow and energy in a control console for providing irrigation fluid and energy to an ultrasonic phacoemulsification handpiece and aspirating fluid from an eye during ocular surgery, the method comprising the steps of:

30 monitoring energy provided to the handpiece;
 monitoring energy removed from the eye by aspirated fluid; and
 calculating, in response to input from the steps of monitoring energy provided and energy removed,
an energy balance over a time interval and regulating the
35 power provided to the handpiece and fluid flow of the irrigation fluid and aspirated fluid.

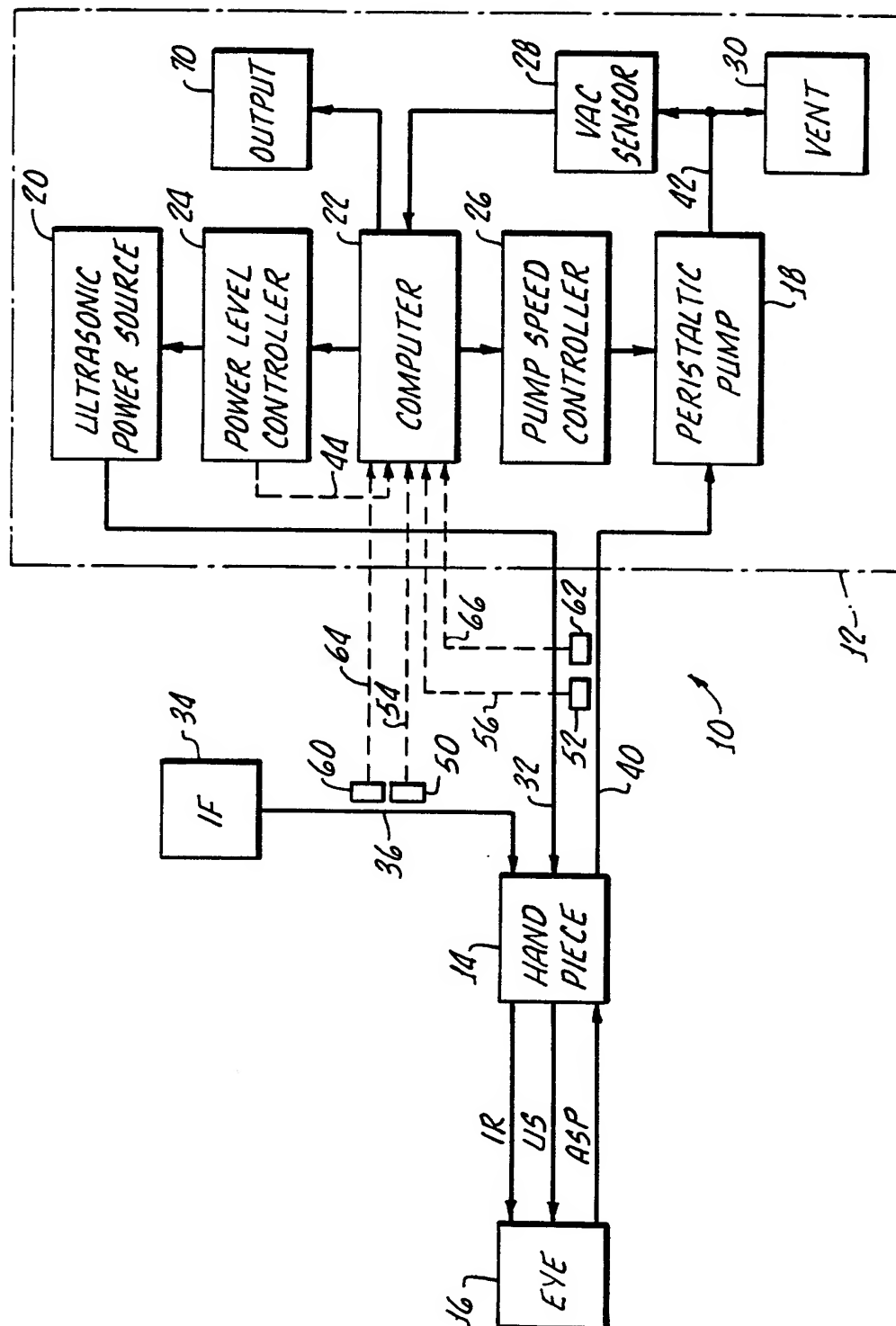


FIG. 1.

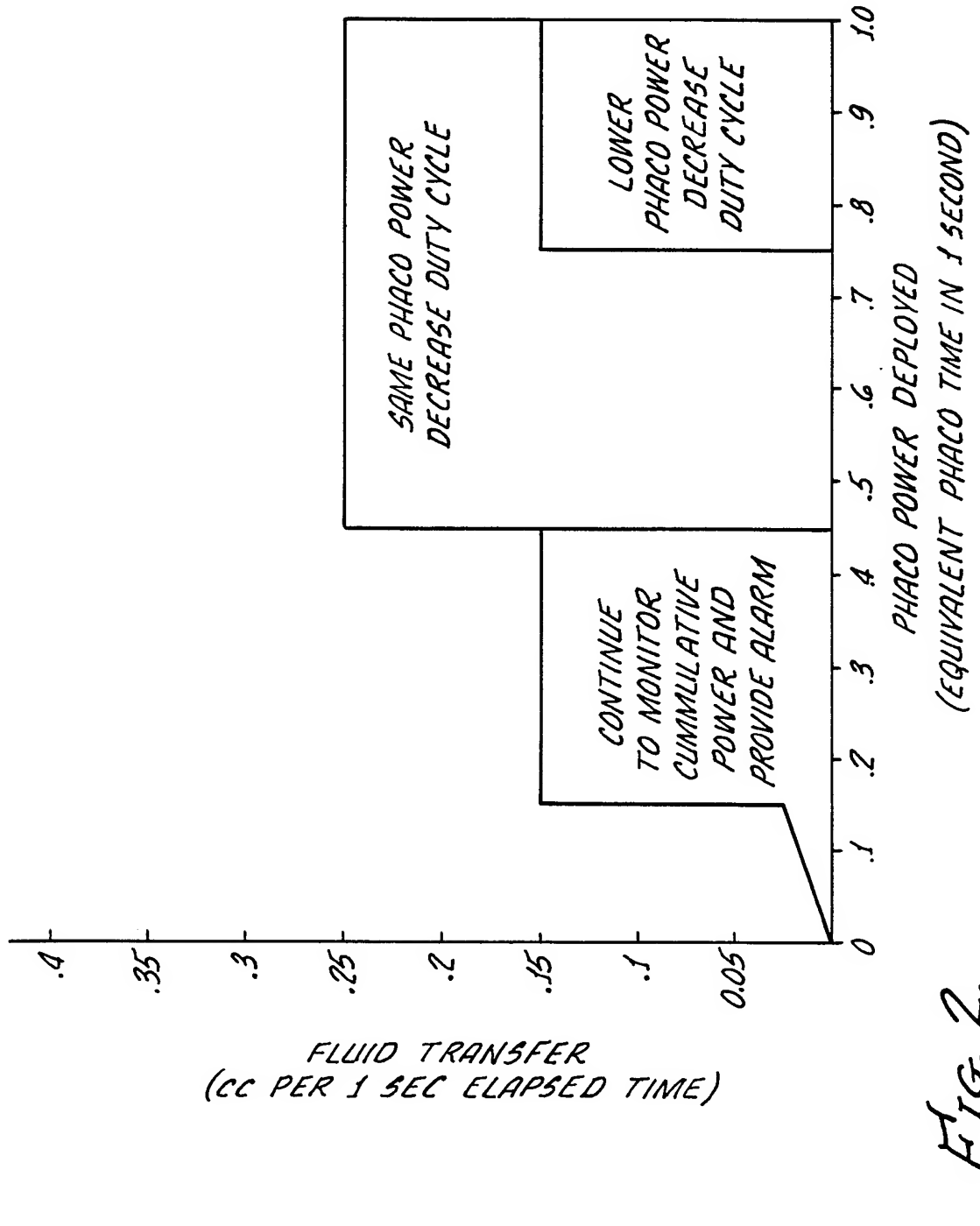


FIG. 2.

INTERNATIONAL SEARCH REPORT

Intern al Application No

PCT/US 99/04494

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61N A61B A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 156 187 A (BRUMBACH JOSEPH F ET AL) 22 May 1979 see column 10, line 40 - line 44; figure 1 see column 14, line 35 - line 37 see column 14, line 58 - line 59 ---	1-5, 7-12, 14-17, 19-21
Y	WO 92 07622 A (BSD MEDICAL CORP) 14 May 1992 see page 31, line 10 - line 25 see page 32, line 33 - line 36; figures 12,13 --- -/--	1-5, 7-12, 14-17, 19-21



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

31 May 1999

Date of mailing of the international search report

07/06/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Mayer, E

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/04494

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 693 613 A (KELMAN CHARLES) 26 September 1972 see column 5, line 1 - line 8; figure 4 ---	1,7,14
A	US 5 569 188 A (MACKOOL RICHARD J) 29 October 1996 see column 5, line 6 - line 17; figure 2 -----	6,13,18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/04494

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4156187 A	22-05-1979	US 4180074 A CA 1092657 A DE 2758909 A FR 2383649 A GB 1591637 A JP 53114285 A US 4184510 A US 4189286 A	25-12-1979 30-12-1980 21-09-1978 13-10-1978 24-06-1981 05-10-1978 22-01-1980 19-02-1980
WO 9207622 A	14-05-1992	US 5344435 A AU 9037891 A CA 2095517 A EP 0556299 A JP 6501411 T	06-09-1994 26-05-1992 06-05-1992 25-08-1993 17-02-1994
US 3693613 A	26-09-1972	NONE	
US 5569188 A	29-10-1996	AU 5540796 A WO 9632144 A	30-10-1996 17-10-1996